



News Release

PO Box 360, Trenton, N.J. 08625-0360

Heather Howard,
Commissioner

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For Further Information, Contact

(609) 984-7160

**Department of Health and Senior Services proposes amendments to N.J.A.C. 8:45-1.3,
Clinical Laboratory Services, Licensure fees and the repeal of N.J.A.C. 8:45-1.4,
Proficiency Testing Fees.**

The Division of Public Health and Environmental Laboratories, Clinical Laboratory and Improvement Services, of the Department of Health and Senior Services is proposing rulemaking to amend N.J.A.C. 8:45-1.3, which establishes licensure fees for clinical laboratories. The proposed rulemaking would also repeal N.J.A.C. 8:45-1.4, which establishes fees for proficiency testing of laboratories conducted by the Department, as well as for the review of proficiency testing results from external proficiency testing programs.

The current fees for the licensure of clinical laboratories at N.J.A.C. 8:45-1.3 have not been changed or increased since 1998. The Department believes it is appropriate to increase the licensure fees by an amount equivalent to the increase of thirty-four percent in the Consumer Price Index for the period January 1998 to January 1999. The proposal would increase the licensure fees paid by clinical laboratories according to the size of the laboratory as determined by its number of employees and the number of specialty areas in which the laboratory provides testing. For example, the fee for a laboratory with one to nine employees would increase from \$100 to \$200 per specialty. For large laboratories with ninety or more employees, the fee would increase from \$200 to \$400 per specialty. The elimination of separate proficiency testing review fees results in a net fee increase for most laboratories that is consistent with the increase in the Consumer Price Index.

The proposal would repeal N.J.A.C. 8:45-1.4 because the Department no longer provides a proficiency testing program for clinical laboratories and the Department will no longer charge fees for review of external proficiency testing results. Clinical laboratories are required to participate in a proficiency testing program approved by the federal Centers for Medicare and Medicaid Services (CMS). Currently, clinical laboratories participate in any CMS-approved proficiency testing program and the testing results are forwarded to the Department for review.

The proposal would also increase the late fee for laboratory renewal applications to \$100.00, and increase the fee for replacement of a license due to a change of address to \$100.00.

The proposal appears in the August 3, 2009 issue of the New Jersey Register.

The public has until October 2, 2009 to comment on the proposal. Persons wishing to comment on the proposal must submit their comments in writing to Ruth Charbonneau, Director,

Office of Legal and Regulatory Affairs, New Jersey Department of Health and Senior Services,
PO Box 360, Trenton, NJ 08625-0360. Written comments on the proposal must be postmarked
on or before October 2, 2009, which is the close of the 60-day public comment period.